UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,649	05/25/2006	Svend Erik Borgesen	BORGESEN4A	5773

1444 7590 01/09/2009

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
01/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,649	BORGESEN, SVEND ERIK	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 34-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 34-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 10, 34-41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,283,934 to Borgesen in view of US 6,585,677 to Cowan.

In the specification and figures, Borgesen discloses the method substantially as claimed by applicant.

With regard to claim 1, Borgesen discloses a method for shunting excess cerebrospinal fluid (which, in excess, comprises a toxic substance) from a brain ventricle to a patient's sinus system, particularly, the saggital sinus (see column 1, lines 10-17, column 2, lines 58-65). The method comprises the steps of providing a shunt system where in the shunt system comprises

- a shunt body 12 allowing fluid communication between a ventricle 14 and saggital sinus 15, wherein the shunt body comprises a valve or flow restricting component 8 (see FIG 8, column 6, column 7, line 65 to column 8, line 25),
- brain ventricle catheter 13 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least FIG 8)
- a sinus catheter (seen generally at reference numeral 7 in FIG 2, unlabeled in FIG 8) connected to the shunt body (see FIG 8), wherein the sinus catheter is

capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor.

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material (see, generally, column 6). Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see column 8, lines 27-47).

Borgesen does not disclose the specific step of treating a patient with a toxic substance within the CSF, nor the step of shunting particular toxins to the sinus system. However, the instantly claimed method provides no steps that differ from those disclosed by Borgesen. That is, both the method disclosed by Borgesen and the instantly claimed method comprise the steps of providing a shunt system with a flow restrictor, brain ventricle catheter, and sinus catheter, inserting the shunt system, and shunting CSF from the brain ventricle to the sinus system. The method disclosed by Borgesen necessarily performs all the steps claimed by Applicant. Accordingly, there is no patentable difference between the method claimed by Applicant and the method disclosed by Borgesen.

With regard to Applicant's recitation of a particular coating on the shunt body, Cowan discloses a CSF shunt that may comprise an adhesion-resistant coating, which corresponds to Applicant's "inert surface preventing biological material from maintaining contact with the inert surface." It would have been obvious to one having ordinary skill in

the art at the time the invention was made to coat the shunt disclosed by Borgesen with an adhesion resistant material as disclosed by Cowan, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 10, Borgesen discloses that the flow restricting structure and the tubes provide a resistance to flow of about 8 to 12 mm Hg/mL/min, which includes values just less than 8 (see column 6, lines 42-45). It is the position of the Examiner that the flow restricting component is *capable* of providing the flow resistance claimed by applicant.

With regard to claim 34, Borgesen discloses that the flow restricting passage comprises a tubular structure (see column 6, line 42).

With regard to claims 35-38, Borgesen discloses that the internal radius of the flow-restricting passage may be 0.15mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see column 6, lines 42-50).

With regard to claim 39, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see column 8, lines 27-47).

With regard to claims 40 and 41, Borgesen discloses a method for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, particularly, the saggital sinus (see column 1, lines 10-17, column 2, lines 58-65).

With regard to claim 43, Borgesen discloses that the apparatus may comprise a check valve 8 (see column 8, line 18).

3. In addition to the rejection presented above, claims 1, 10, and 34-47, are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0045847 to Borgesen.

With regard to claim 42, Borgesen discloses a method for shunting excess cerebrospinal fluid (which, in excess, comprises a toxic substance) from a brain ventricle to a patient's sinus system, which may comprise the transverse sinus (see paragraphs 0002, 0003, 0058). The method comprises the steps of providing a shunt system where in the shunt system comprises

- a shunt body 10 allowing fluid communication between a ventricle 21 and ventricular sinus, wherein the shunt body comprises a flow restricting component 16 (see FIG 8, paragraph 0052),
- brain ventricle catheter 15 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least paragraph 0053)
- a sinus catheter 18 (se at least paragraph 0055) connected to the shunt body, wherein the sinus catheter is capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material (see, generally, paragraph 0052). Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see page 6, claim 26).

Borgesen does not disclose the specific step of treating a patient with a toxic substance within the CSF, nor the step of shunting particular toxins to the sinus system. However, the instantly claimed method provides no steps that differ from those disclosed by Borgesen. That is, both the method disclosed by Borgesen and the instantly claimed method comprise the steps of providing a shunt system with a flow restrictor, brain ventricle catheter, and sinus catheter, inserting the shunt system, and shunting CSF from the brain ventricle to the sinus system. The method disclosed by Borgesen necessarily performs the steps claimed by Applicant. Accordingly, there is no patentable difference between the method claimed by Applicant and the method disclosed by Borgesen.

With regard to Applicant's recitation of a particular coating on the shunt body, Cowan discloses a CSF shunt that may comprise an adhesion-resistant coating, which corresponds to Applicant's "inert surface preventing biological material from maintaining contact with the inert surface." It would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the shunt disclosed by Borgesen with an adhesion resistant material as disclosed by Cowan, since it has been held to be

within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 10, Borgesen discloses that the flow restricting structure and the tubes provide a resistance to flow of less than 8 mm Hg/mL/min (see paragraph 0031).

With regard to claim 34, Borgesen discloses that the flow restricting passage comprises a tubular structure (see paragraph 0026).

With regard to claims 35-38, Borgesen discloses that the internal radius of the flow-restricting passage may be less than 0.20mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see paragraphs 0033, 0035, 0036).

With regard to claim 39, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see, generally, claim 26).

With regard to claims 40 and 41, Borgesen discloses a method for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, particularly, the saggital sinus (see at least paragraph 0052).

With regard to claims 43-47, Borgesen discloses that the apparatus may comprise a ball check valve wherein the check valve provides no fluid resistance to the

CSF, rendering fluid flow resistance independent of the check valve with the check valve operating independently of the fluid pressure threshold (see paragraph 0040).

4. Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,283,934 to Borgesen in view of US 6,585,677 to Cowan et al, further in view of US 6,383,159 to Saul et al.

In the specification and figures, the cited prior art discloses the method substantially as claimed by applicant (see rejection above).

With regard to claims 2-8, Borgesen fails to disclose that the condition related to the accumulation of CSF and its assorted potentially toxic substances may comprise several specific conditions. However, Saul discloses a device and method for treating patients wherein the CSF of a selected patient may comprise a toxin that results in lesions of the brain. Saul discloses that the conditions that may be treated by the disclosed method comprise Alzheimer's disease, Down's Syndrome, hereditary cerebral hemorrhage with amyloidosis of the Dutch-Type, epilepsy, Parkinson's disease, polyneuropathies, and Guillain-Barre –Syndrome (See column 3, lines 28-46). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method disclosed by Borgesen to treat patients at risk of the conditions listed by Saul, since Saul discloses that such conditions may be treated by shunting excess toxins from a patient's brain.

With regard to claim 9, Saul discloses that the toxic substance removed by shunting may comprise tau or alpha-beta 42 (see column 1, lines 37-42) in order to

forestall the onset or progression of various ailments. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method disclosed by Borgesen to remove the toxins disclosed by Saul, since Saul discloses that such toxins may be removed in order to forestall the onset or progression of various ailments.

5. In addition to the rejection presented above, claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0045847 to Borgesen in view of US 6,585,677 to Cowan et al, further in view of US 6,383,159 to Saul et al.

In the specification and figures, Borgesen discloses the method substantially as claimed by applicant (see rejection above).

With regard to claims 2-8, Borgesen fails to disclose that the condition related to the accumulation of CSF and its assorted potentially toxic substances may comprise several specific conditions. However, Saul discloses a device and method for treating patients wherein the CSF of a selected patient may comprise a toxin that results in lesions of the brain. Saul discloses that the conditions that may be treated by the disclosed method comprise Alzheimer's disease, Down's Syndrome, hereditary cerebral hemorrhage with amyloidosis of the Dutch-Type, epilepsy, Parkinson's disease, polyneuropathies, and Guillain-Barre –Syndrome (See column 3, lines 28-46). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method disclosed by Borgesen to treat patients at risk of the

conditions listed by Saul, since Saul discloses that such conditions may be treated by shunting excess toxins from a patient's brain.

With regard to claim 9, Saul discloses that the toxic substance removed by shunting may comprise tau or alpha-beta 42 (see column 1, lines 37-42) in order to forestall the onset or progression of various ailments. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the method disclosed by Borgesen to remove the toxins disclosed by Saul, since Saul discloses that such toxins may be removed in order to forestall the onset or progression of various ailments.

Response to Arguments

6. Applicant's arguments, filed 5 November 2008, with respect to the rejection(s) of the pending claim(s) under Borgesen have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Borgesen and Cowan, as presented above.

7. The Examiner inadvertently failed to specifically address claims 7 and 8 in the prior office action. However, the Examiner notes that the limitations of claims 7 and 8 are clearly suggested by Saul, and are expressly pointed out in the 5 May rejection and above.

8. Applicant argues that in the context of the present application, CSF itself is not the toxic substance to be shunted to a patient's sinus. The Examiner understands this

argument. However, Applicant has not claimed any steps that differ from the shunting steps disclosed by the prior art. In other words, the provision of a shunt, inserting the shunt within a patient, and shunting CSF as disclosed by Borgesen necessarily shunts any toxic substances that are within the CSF. Accordingly, the instantly claimed method is patentably indistinct from the method suggested by the prior art.

9. Applicant argues that Borgesen fails to disclose the step of providing a shunt with the claimed "plurality of charged species." The Examiner notes that this step is claimed in the alternative to the step of providing a shunt with an "inert surface." As such, no charged species are required by the present claims. With regard to the inert surface, the Examiner has applied the Cowan reference.

10. Applicant argues that Saul does not disclose the step of providing a coated shunt. The Examiner has applied the Cowan reference to cure this deficiency.

11. Applicant argues that the valve disclosed by Borgesen '934 is not suitable for shunting CSF when there is no excess CSF to open the valve. However, the Applicant claims that the valve may support opening pressures of up to 8mmHg, which corresponds with the minimum opening pressure disclosed by Borgesen. Accordingly, the Borgesen valve would be capable of operating in the method claimed by Applicant. Furthermore, Applicant has not set forth any steps or conditions that establish that the patient has a normal CSF pressure. Accordingly, the cited prior art suggests the claimed method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
7 January 2008